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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/734,583

12/15/2003

Hidetoshi Andou

2923-595

2600

6449

7590

06/04/2008

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EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1647

NOTIFICATION DATE

DELIVERY MODE

06/04/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/734,583	Applicant(s) ANDOU ET AL.	
	Examiner Marianne P. Allen	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 16-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-8, 12-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 12-15 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/13/2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 18 was added in the amendment filed 1/5/07. Claims 19-20 were added in the amendment filed 1/19/07. These claims have been subsequently amended.

The originally filed specification and claims do not appear to contemplate a process of obtaining a solution containing a purified refolded biologically active monomeric bone morphogenetic factor, wherein said solution is free from oligomeric side products having the steps set forth in the claims.

Art Unit: 1647

Applicant has now pointed to pages 5, 12, 9-10, and 16-17. This is not agreed with. Claim 18 is generic to any bone morphogenetic factor whereas the disclosure of being free from oligomeric side products is particular to a specific MP52 variant purified under particular conditions (see Figures 2-3 referenced by applicant). The general concept recited in the claims is not contemplated or disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 16-20 are rejected under 35 U.S.C. 103(a) as being obvious over Andou et al. (U.S. Patent No. 6,551,801) in view of Hotten et al. (U.S. Patent No. 6,972,321).

This rejection is maintained for reasons of record. Applicant has argued that these two patents are not “by another” and cannot be applied as prior art. Applicant has submitted a 1.132 declaration and stated that the instant invention was derived from these two patents. The declaration does not provide any showing. It only provides an unsupported statement. It is not clear what specific parts of each patent (column and line number) are being referred to nor which inventor is being associated with each concept (attribution). No derivation of the instant invention in its entirety is shown. Applicant has been directed to MPEP 2146 and 706.02(l)(1). The declaration submitted does not satisfy the requirements set forth therein. Applicant has not established that the subject matter in the issued patents and the claimed invention were, at the time the claimed

Art Unit: 1647

invention was made, owned by the same person or subject to an obligation of assignment to the same person. Applicant has not established that the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made; the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and the application for patent for the claimed invention discloses the names of the parties to the joint research agreement.

The present situation differs from the situation set forth in MPEP 715.01(a) and (c) or MPEP 716.10. These situations concern a prior art document with multiple inventors (i.e. S plus additional inventors) where the instant application names only one of the inventors (i.e. S alone) and the declaration establishes that the portion of the disclosure applied against the instant application was attributable to S alone thereby establishing the same inventive entity (not by other). There are six inventors named on the instant application. Three are named on the first patent assigned to one assignee and the remaining three are named on the second patent to a second assignee. Neither patent has a common inventor. Neither patent contemplates the complete invention as is presently claimed. The patents contemplate different subparts or aspects of the claimed invention.

The presently claimed subject matter is not found in any of the parent applications except 10/414,954, filed 4/16/03. No other prior application teaches all limitations of the claims. As such, the effective filing date of the instant application is 4/16/03. Both Andou et al. and Hotten et al. are by other as the inventive entities are not identical to that of the instant application. They remain valid prior art against the instant claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1647

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa